

AMENDMENTS TO THE SPECIFICATION

In the Specification at page 11, paragraph [0047], last line, please enter the following amendment: assembly [[30]] 20.

In the Specification at page 11, paragraph [0049], second line, please enter the following amendment: ~~plug~~ plunger 18.

In the Specification at page 13, please amend paragraph [0053] as follows:

[0053] Fig. 2 illustrates one embodiment of an actuation/activation device 130 of the present invention. Device 130 includes a trocar or elongated tube 132 and a handle 134 attached at a proximal end 144 of trocar 132. Trocar 132 defines a lumen therein and preferably has a pointed and sharp distal end 146 to facilitate penetration into the patient, such as into the sub-dermal tissue. Coaxially aligned within the lumen of trocar 132, from open distal 146 to proximal end 144, are a first load member 142, a load spacer 140, a second load member 138 and a push rod 136. The push rod holds the implant in place while the user retracts the trocar. Second load member 138 provides a resistive load which is greater than first load member, 142, typically about 2 to about 10 about times greater where the first load member has a resistive load in the range from about 0.5 to about 10 N [[lbf]]. In the embodiment illustrated in Fig. 2, the load members are in the form of springs where first load member 142 is a light spring having a resistive load of about 1 N [[lbf]] and second load member 138 is a heavy spring having a resistive load of about 5 N [[lbf]].

In the Specification at page 14, please amend paragraph [0055] as follows:

[0055] At the proximal end of push rod 136 is locking mechanism 52 for locking onto push rod 136 when sufficient force is applied to the coaxially aligned assembly. Locking mechanism 52 is also biased requiring a minimum force or load equivalent to the combined resistive loads of first load member and second load member in order to overcome the bias and lock onto rod 136. Trocar 132 further includes an implant restraining mechanism such as a leaf spring located within the wall of trocar 132 in the general area indicated by reference arrow 60. The restraining mechanism serves to retain the implant within the trocar once the implant is translated past it in a proximal direction. Device 130 further includes a lever 148 attached at its base to a tubular segment 56. Tubular segment 56 resides coaxially about rod 136 and is translatable within a channel 50 along the length of rod 136 from a first, engaged or loaded position, *i.e.*, prior to operative loading of an implant, to a second, unengaged or unloaded position, as shown in Fig. 2. The change in position of the lever is performed manually.

In the Specification at page 14, paragraph [0056], second to last line, please enter the following amendment: aspects and properties of device 70 are similar to those of device 130 of Fig. 2, the latter.

In the Specification at page 15, please amend paragraph [0058] as follows:

[0058] Prior to use, the implant will typically be contained in a channel of a sterile vial, such as vial 100 in Fig. 4, and positioned within the channel 102 such that the valve or actuation/activation mechanism (in this case, the orifice end) of the implant is at the top end or mouth 104 of vial 100 (or optionally it may alternatively be at the bottom end of the vial). Holding handle 134 of device 130, the user inserts the distal end of trocar 56 into channel 102 of vial 100 such that the exposed end of the implant (not shown) is

inserted into distal end of the trocar 56 and engages light spring 142. (Of course, the implant may be handled directly by the user and manually inserted into the trocar; however, such may not be preferred as it may comprise the sterility of the implant.) The user will continue to push forward on the trocar handle with sufficient compressive force such that the implant is caused to translate proximally within the trocar lumen, compressing against light spring 142 which in turn compresses against load spacer 140 which in turn compresses against heavy spring 138 which in turn compresses against rod 136 until sufficient force is placed against locking mechanism 52 causing it to lock.

In the Specification at page 15, please amend paragraph [0059] as follows:

[0059] The trocar is designed such that the total resistive load within its lumen, *i.e.*, the compressive load required to actuate locking mechanism 52, is greater than the compressive load required to actuate/activate the implant, in this case, to push the valve in. This is to ensure that the implant cannot be completely loaded until it is activated in order to avoid implanting an inactivated implant. An inactivated implant would provide no beneficial effect to the patient. Thus, when sufficient compressive force, *e.g.*, 2.5 N [[lbf]], is applied to the implant and in turn on the loaded assembly within the trocar, the implant is actuated. An additional compressive force, *e.g.*, 5 N [[lbf]], is then required to overcome the total resistive force, *e.g.*, 7.5 N [[lbf]], of the load members in order to actuate locking mechanism 52. The locking mechanism may be designed to provide tactile or auditory feedback (such as a “click”) to indicate to the user that the locking mechanism has been activated. The linear translation required by the implant in order to provide such additional compressive force causes the implant to translate past the implant restraining member 60, thereby preventing the implant from translating distally back out of the trocar until positive action is taken by the user, *i.e.*, until lever 48 is actuated. Requiring an additional force to load the implant ensures that the implant is activated and properly loaded. If an insufficient amount of additional force is applied, wherein the retaining mechanism has not been engaged, the resulting counter force of the load

members will eject the implant out of the trocar. The implant is now properly loaded within the trocar and is activated so that, upon implant, delivery of the beneficial agent will commence.